

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

RETRACTABLE §
TECHNOLOGIES, INC., et al. §
v. § Case No. 2:08-CV-16-LED-RSP
§
BECTON, DICKINSON AND CO. §

MEMORANDUM ORDER

Plaintiff Retractable Technologies, Inc. (“RTI”) alleges violations of the Sherman and Clayton Acts, violations of the Texas Antitrust Act, false advertising in violation of the Lanham Act, product disparagement, tortious interference with prospective contract or business relations, and unfair competition by Defendant Becton, Dickinson and Company (“BD”). (Dkt. No. 73.) Before the Court is RTI’s Motion to Limit the Testimony of Defendant’s Expert Mr. Timothy A. Ulatowski. (Dkt. No. 176, filed January 12, 2012.)

APPLICABLE LAW

An expert witness may provide opinion testimony if “(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702.

Rule 702 requires a district court to make a preliminary determination, when requested, as to whether the requirements of the rule are satisfied with regard to a particular expert’s proposed testimony. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592-93 (1993). District courts are accorded broad

discretion in making Rule 702 determinations of admissibility. *Kumho Tire*, 526 U.S. at 152 (“the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable”). Although the Fifth Circuit and other courts have identified various factors that the district court may consider in determining whether an expert’s testimony should be admitted, the nature of the factors that are appropriate for the court to consider is dictated by the ultimate inquiry—whether the expert’s testimony is sufficiently reliable and relevant to be helpful to the finder of fact and thus to warrant admission at trial. *United States v. Valencia*, 600 F.3d 389, 424 (5th Cir. 2010).

Importantly, in a jury trial setting, the Court’s role under *Daubert* is not to weigh the expert testimony to the point of supplanting the jury’s fact-finding role; instead, the Court’s role is limited to that of a gatekeeper, ensuring that the evidence in dispute is at least sufficiently reliable and relevant to the issue before the jury that it is appropriate for the jury’s consideration. *See Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1391-92 (Fed. Cir. 2003) (applying Fifth Circuit law) (“When, as here, the parties’ experts rely on conflicting sets of facts, it is not the role of the trial court to evaluate the correctness of facts underlying one expert’s testimony.”); *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 249-50 (5th Cir. 2002) (“[t]he trial court’s role as gatekeeper [under *Daubert*] is not intended to serve as a replacement for the adversary system.’ . . . Thus, while exercising its role as a gate-keeper, a trial court must take care not to transform a *Daubert* hearing into a trial on the merits,” quoting Fed. R. Evid. 702 advisory committee note). As the Supreme Court explained in *Daubert*, 509 U.S. at 596, “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *See Mathis v. Exxon Corp.*, 302 F.3d 448, 461 (5th Cir. 2002).

DISCUSSION

RTI seeks to wholly exclude Mr. Ulatowski from testifying as an expert in this case. (Mot. at 1.) RTI objects to Mr. Ulatowski's proposed testimony on several grounds.

1. RTI objects to Mr. Ulatowski's proposed testimony regarding FDA 510(k) clearance. RTI's objections are primarily targeted to the relevance and unfair prejudice issues of the FDA 510(k) clearance evidence. The Court addressed these issues in its Orders on the Parties' Motions in Limine. (*See* Dkt. No. 481 and 488.) RTI also alleges that Mr. Ulatowski's opinions regarding the 510(k) process are unreliable, pointing out alleged shortcomings not with Mr. Ulatowski's opinions or the basis for those opinions, but with the 510(k) process itself. (Mot. at 8.) RTI provides no reason that those issues cannot be properly addressed through vigorous cross examination of Mr. Ulatowski. *See Mathis v. Exxon Corp.*, 302 F.3d at 461.

2. RTI also objects to Mr. Ulatowski's proposed testimony regarding OSHA regulations. RTI's objections are primarily targeted to the relevance and unfair prejudice issues of the OSHA evidence. The Court addressed these issues in its Orders on the Parties' Motions in Limine. (*See* Dkt. No. 481 and 488.) RTI also attacks Mr. Ulatowski on the grounds that Mr. Ulatowski "spent his entire career working at the FDA and never worked for OSHA, at an entity that had to comply with OSHA requirements, or any other division or section of the [DHHS] other than the FDA." (Mot. at 9-10.) RTI does not state why it believes that this is a reason for exclusion, nor any case law to cite for the proposition that an expert must have been employed within a specific division of a government agency in order to have sufficient knowledge regarding that division's practices. RTI also alleges that Mr. Ulatowski's opinion "is not based on sufficient facts or data," but provides almost no reasoning to support that conclusion, providing only a note that one of the citations provided by Mr. Ulatowski contains a disclaimer that listing does not constitute an endorsement. (Mot. at 10.) RTI provides no reason that those

issues cannot be properly addressed through vigorous cross examination of Mr. Ulatowski. *See Mathis v. Exxon Corp.*, 302 F.3d at 461.

3. RTI also objects to Mr. Ulatowski's proposed testimony regarding MDRs and procedures, alleging that they are allegedly irrelevant, unreliable, and unduly prejudicial. (Mot. at 10-12.) BD alleges through Mr. Ulatowski's testimony that RTI "failed to report those serious injuries and malfunctions to the FDA, despite being required ... to do so." (Resp. at 11.) BD states that this is relevant "to RTI's claim that its products are medically superior to BD's..." (*Id.*) Because the jury will be hearing extensive evidence about MDRs, there is no danger of undue prejudice from testimony concerning RTI's failures, and they are relevant to put in context the seriousness, *vel non*, of BD's failures to report.

4. RTI also objects to Mr. Ulatowski's opinion that BD's complaint procedures comply with FDA requirements as irrelevant. (Mot. at 14.) The Court disagrees, and notes that BD's compliance is relevant for a multitude of reasons.

5. RTI finally lodges a general objection, stating that "testimony regarding opinions not set forth in the expert report should be excluded." (Mot. at 15.) The Court finds this objection is too vague to base any action upon it, but notes that if an expert attempts to testify on matters not covered in an expert report, the parties may raise the issue with the Court at that time.

CONCLUSION

Having considered all of RTI's objections to Mr. Ulatowski's opinions and proposed testimony, RTI's Motion to Limit the Testimony of Plaintiff's Expert Mr. Timothy Ulatowski (Dkt. No. 176) is **DENIED**.

SIGNED this 26th day of August, 2013.



ROY S. PAYNE
UNITED STATES MAGISTRATE JUDGE